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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/526,425

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Tsuneko Okazaki

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EDWARDS ANGELL PALMER & DODGE LLP

P.O. BOX 55874

BOSTON, MA 02205

EXAMINER

HILL, KEVIN KAI

ART UNIT

PAPER NUMBER

1633

MAIL DATE

DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/526,425	OKAZAKI ET AL.	
	Examiner	Art Unit	
	KEVIN K. HILL	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 January 2011.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,4,14,57 and 58 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,4,14,57 and 58 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Detailed Action Election/Restrictions

Applicant's response to the Requirement for Restriction, filed on October 1, 2007 is acknowledged.

Applicant has elected with traverse the invention of Group I, claim(s) 1, 3-7 and 13-14, drawn to a method of producing a circular mammalian artificial chromosome.

Within Group I, Applicant has elected the insertion sequence species "lox P site", as recited in Claim 13.

Amendments

Applicant's response and amendments, filed January 24, 2011, to the prior Office Action is acknowledged. Applicant has cancelled Claims 2-3, 5-13 and 15-56, and amended Claim 1.

Claims 1, 4, 14 and 57-58 are under consideration.

Priority

This application is a 371 of PCT/JP03/11134, filed September 1, 2003. Acknowledgment is made of Applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). Certified copies of the foreign patent applications Japan 2002-258114, filed September 3, 2002 and Japan 2002-338865, filed November 22, 2002 are filed with the instant application. Certified English translations of said foreign applications have not been provided.

Examiner's Note

Unless otherwise indicated, previous objections/rejections that have been rendered moot in view of the amendment will not be reiterated. The arguments in the January 24, 2011 response will be addressed to the extent that they apply to current rejection(s).

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 103

1. **The prior rejection of Claims 1, 4 and 57 under 35 U.S.C. 103(a)** as being unpatentable over Mejia et al (Genomics 70(2):165-170, 2000; *of record in IDS, AE), in view of Perkins et al (US 2003/0119104 A1), Waye et al (Mol. and Cell. Biol. 6(9):3156-3165, 1986), Ikeno et al (Human Mol. Gen. 3(8):1245-1257, 1994; *of record in IDS, CE), Ikeno et al (Nature Biotech. 16:431-439, 1998; of record in IDS) and Bigger et al (J. Biol. Chem. 276(25):23018-23027, 2001) **is withdrawn** in light of Applicant's amendment to the claims to recite the size of the mammalian centromere sequence is about 50Kb or less, a limitation that neither Mejia et al, Perkins et al, Waye et al, Ikeno et al (1994, 1998) nor Bigger et al teach.

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2. **Claims 1, 4 and 57 stand rejected under 35 U.S.C. 103(a)** as being unpatentable over Mejia et al (Genomics 70(2):165-170, 2000; *of record in IDS, AE), in further view of Waye et al (Mol. and Cell. Biol. 6(9):3156-3165, 1986), Ikeno et al (Human Mol. Gen. 3(8):1245-1257, 1994; *of record in IDS, CE), Perkins et al (US 2003/0119104 A1), Ikeno et al (Nature Biotech. 16:431-439, 1998; of record in IDS) and Bigger et al (J. Biol. Chem. 276(25):23018-23027, 2001), as applied to claims 1, 4 and 57 above, and in further view of Bokkelen et al (U.S. Patent No. 5,695,967) for reasons of record.

Response to Arguments

Applicant argues that Ikeno does not indicate that 20kb fragment may exist as a functional unit in itself, let alone availability nor utility thereof. Thus, claiming a small-sized (i.e. "about 50kb or less") centromere sequence is novel and beyond the expectation of a person skilled in the art in consideration of the common knowledge.

Applicant's argument(s) has been fully considered, but is not persuasive.

As a first matter, in response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). In the instant case, Bokkelen et al disclosed a means of cloning iterations of mammalian centromeric alphoid DNA 2.7kb higher order repeats, e.g. 2.7kb, 5.4kb, 11kb, 22kb, 43kb, 86kb, 130kb and 174kb iterations (Figure 1; col. 6, lines 22-25). In the case where the claimed ranges "overlap or lie inside ranges disclosed by the prior art" a prima facie case of obviousness exists. *In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976); *In re Woodruff*, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. Cir. 1990). It is routine procedure to optimize component amounts to arrive at an optimal product that is superior for its intended use, since it has been held where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. See M.P.E.P. §2144.05.

As a second matter, the focus when making a determination of obviousness should be on what a person of ordinary skill in the pertinent art would have known at the time of the invention, and on what such a person would have reasonably expected to have been able to do in view of that knowledge. This is so regardless of whether the source of that knowledge and ability was documentary prior art, general knowledge in the art, or common sense. M.P.E.P. §2141.

The person of ordinary skill in the art is a hypothetical person who is presumed to have known the relevant art at the time of the invention. Factors that may be considered in determining the level of ordinary skill in the art may include: (1) "type of problems encountered in the art;" (2) "prior art solutions to those problems;" (3) "rapidity with which innovations are made;" (4) "sophistication of the technology; and" (5) "educational level of active workers in the field. In a given case, every factor may not be present, and one or more factors may predominate." *In re GPAC*, 57 F.3d 1573, 1579, 35 USPQ2d 1116, 1121 (Fed. Cir. 1995); *Custom Accessories, Inc. v. Jeffrey-Allan Industries, Inc.*, 807 F.2d 955, 962, 1 USPQ2d 1196, 1201 (Fed. Cir. 1986); *Environmental Designs, Ltd. V. Union Oil Co.*, 713 F.2d 693, 696, 218 USPQ 865, 868 (Fed. Cir. 1983).

In the instant case, and to rebut Applicant's assertion regarding the common knowledge of the ordinary artisan at the time of the instantly asserted invention, the Examiner provides Applicant's own work (Okazaki and Ikeno et al; WO 98/008964; curiously omitted from Applicant's Information Disclosure Statements) disclosing years before the instantly filed application a method of making mammalian artificial chromosomes comprising the use of a mammalian centromere sequence comprising an 11-mer repeat unit obtained from human chromosome 21 and that is 40Kb, 70Kb or 100Kb (Figure 3).

Thus, contrary to Applicant's assertion, the use of a mammalian centromere sequence comprising an 11-mer repeat unit obtained from human chromosome 21 and that is "about 50Kb or less" for the production of a mammalian artificial chromosome is neither novel nor beyond the expectation of the ordinary artisan.

3. **Claim 14 stands rejected under 35 U.S.C. 103(a)** as being unpatentable over Mejia et al (Genomics 70(2):165-170, 2000; *of record in IDS, AE), in further view of Waye et al (Mol. and Cell. Biol. 6(9):3156-3165, 1986), Ikeno et al (Human Mol. Gen. 3(8):1245-1257, 1994; *of record in IDS, CE), Perkins et al (US 2003/0119104 A1) Ikeno et al (Nature Biotech. 16:431-439, 1998; of record in IDS), Bigger et al (J. Biol. Chem. 276(25):23018-23027, 2001) and Bokkelen et al (U.S. Patent No. 5,695,967), as applied to claims 1, 4, 7 and 57 above, and in further view of Cooke et al (WO 00/18941).

4. **Claim 58 stands rejected under 35 U.S.C. 103(a)** as being unpatentable over Mejia et al (Genomics 70(2):165-170, 2000; *of record in IDS, AE), in further view of Waye et al (Mol. and Cell. Biol. 6(9):3156-3165, 1986), Ikeno et al (Human Mol. Gen. 3(8):1245-1257, 1994; *of record in IDS, CE), Perkins et al (US 2003/0119104 A1) Ikeno et al (Nature Biotech. 16:431-

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439, 1998; of record in IDS), Bigger et al (J. Biol. Chem. 276(25):23018-23027, 2001), Bokkelen et al (U.S. Patent No. 5,695,967) and Cooke et al (WO 00/18941), as applied to claims 1, 4, 7, 14 and 57 above, and in further view of Okazaki et al (WO 98/08964).

Conclusion

5. No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Kevin K. Hill whose telephone number is 571-272-8036. The Examiner can normally be reached on Monday through Friday, between 9:00am-6:00pm EST.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Joseph T. Woitach can be reached on 571-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Kevin K. Hill/

Primary Examiner, Art Unit 1633